



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/628,880	07/28/2003	Neal L. Eigler	CEDAR.001A	3872

20995 7590 07/08/2010
KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER

RYCKMAN, MELISSA K

ART UNIT	PAPER NUMBER
----------	--------------

3773

NOTIFICATION DATE	DELIVERY MODE
-------------------	---------------

07/08/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
efiling@kmob.com
eOAPilot@kmob.com

Office Action Summary	Application No. 10/628,880	Applicant(s) EIGLER ET AL.	
	Examiner MELISSA RYCKMAN	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 June 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-31,33,34,78-81,97,98,107 and 108 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-31,33,34,78-81,97,98,107 and 108 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The indicated allowability of claims 27-31, 33, 34, 78-81 and 108 is withdrawn in view of the newly discovered reference to Goldfarb et al. (U.S. Patent No. 6,752,813). Rejections based on the newly cited reference follow.

The finality of the office action dated 4/5/10 has been withdrawn due to the new art rejection. This office action is still in response to the amended claims filed 12/15/09

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 27-31, 33, 34, 78-81, 97, 98, 107, and 108 are rejected under 35 U.S.C. 103(a) as being unpatentable over Modesitt et al. (U.S. Patent No. 6,136,010) in view of Kuehn et al. (US 6165183) and Goldfarb et al. (U.S. Patent No. 6,752,813).

Modesitt teaches a catheter capable of accessing the heart and engaging a heart valve comprising:

- an elongate body (12) having a proximal and a distal end; the elongate body having housed therein a fastening material (34) configured to suture two heart leaflets together (capable of being used in the heart, Fig. 11D); an anchor zone (22) on a distal portion of the body, and at least one tissue manipulator (24) carried by the flexible body proximally of the anchor zone (Fig. 5), the tissue

Art Unit: 3773

manipulator having a fixed end (col. 9, ll. 1-3, each half of the tissue manipulators are affixed together) and a free end (ends near 52 in Fig. 12B), the free end being moveable to an extended position in which the free end is proximal of the fixed end (Fig. 13), the tissue manipulator being disposed at an angle not more than 90 degrees with respect to the elongate flexible body when in the extended position (Fig. 13E); the anchor zone is configured to orient and anchor the catheter so that the at least one tissue manipulator (440) can be positioned at the valve (Fig. 21).

- A fastening material adapted for use in suturing two leaflets of a heart, the fastening material being housed within the distal portion
- The minimum length of the anchor zone is at least 10 cm (col. 8, ll. 5,6 using the needles as a reference the anchor zone is clearly at least 10 cm).
- wherein the tissue manipulator is moveable between an axial orientation (Fig. 12A) for transluminal navigation and an inclined orientation (Fig. 12B) for manipulating tissue.
- wherein the first tissue manipulator (24) comprises a tissue grasper (38) for grasping a heart valve leaflet.
- at least a first component (24), which is axially moveable with respect to a second component (Fig. 12B)
- at least one needle capturing device coupled with the end of the fastening material (Fig. 13E)

Art Unit: 3773

- the fastening material is partially housed within the tissue manipulator (Fig. 13E) and distal the tissue manipulator (Fig. 13E)
- the catheter having a length sufficient to reach the heart from a femoral vein access
- the first and second tissue manipulators (as shown when in use in Fig. 13E) are asymmetric, the first tissue manipulator is longer than the second tissue manipulator (see Fig. 13E)
- a two receptacle located within the first and second tissue manipulators for receiving a first/second fixating member (52, Fig. 12B)
- a first end of a fastening material is coupled with the first receptacle and a second end of the fastening material is coupled with the second receptacle (resulting in Figs. 13 E and F)
- the tissue manipulator comprises a first elongate tissue manipulator having a first length and a second tissue manipulator having a second length (as seen in Fig. 13E), the first and second tissue manipulators both configured to engage portions of a heart valve from the same side of the valve, the second length being greater than the first length (capable of being used as described)

Modesitt teaches the claimed invention as described above but is silent regarding the material choice for the shaft, 12. However Cribier teaches an interventional catheter for accessing the heart wherein elongate body if flexible (Fig. 8) and is configured to bend in order to access the heart and bend through the arteries. It

Art Unit: 3773

would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Modesitt with flexible body of Cribier in order to access a wide variety of medical problems that require passage through tortuous pathways in the body.

Modesitt teaches the claimed invention but does not teach the two tissue manipulators being moved independently of each other, however Goldfarb teaches independently movable arms (Fig. 14). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use independently movable arms as this aids in positioning the fasteners in the correct location.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection dated 12/15/09 presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

Art Unit: 3773

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA RYCKMAN whose telephone number is (571)272-9969. The examiner can normally be reached on a flexible schedule, email address is melissa.ryckman@uspto.gov.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571)-272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Application/Control Number: 10/628,880
Art Unit: 3773

Page 7

MKR
/Melissa Ryckman/
Examiner, Art Unit 3773

/Darwin P. Erez/
Primary Examiner, Art Unit 3773